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=> immunization
L7      87180 IMMUNIZATION

=> L1 and L7
L8      19 L1 AND L7

=> HIV and L8
L9      0 HIV AND L8

=> HSV and L8
L10     0 HSV AND L8

=> papilloma and L8
L11     0 PAPILLOMA AND L8

=> candida and L8
L12     0 CANDIDA AND L8

=> HBV and L8
L13     0 HBV AND L8

=> treponema and L8
L14     0 TREPONEMA AND L8

=> gonoccal and L8
L15     0 GONOCAL AND L8

=> chlamydia and L8
L16     0 CHLAMYDIA AND L8

=> D L8 IBIB TI SO AU ABS 1-19
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L8 ANSWER 12 OF 19 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN  
 ACCESSION NUMBER: 2001:387359 BIOSIS  
 DOCUMENT NUMBER: PREV200100387359  
 TITLE: Hepatitis B vaccine in infants: A randomized controlled trial comparing gluteal versus anterolateral thigh muscle administration.  
 AUTHOR(S): Alves, Andrea Santos Rafael; Nascimento, Cristiane M. R.; Granato, Celso H.; Sato, Helena Keiko; Morgato, Marina F.; Pannuti, Claudio S. [Reprint author]  
 CORPORATE SOURCE: Av. Dr. Eneas de Carvalho Aguiar 470, 05403-000, Sao Paulo, SP, Brazil  
 SOURCE: cpannuti@usp.br  
 Revista do Instituto de Medicina Tropical de Sao Paulo, (May-June, 2001) Vol. 43, No. 3, pp. 139-143. print.  
 CODEN: RMTSAE. ISSN: 0036-4665.  
 DOCUMENT TYPE: Article  
 LANGUAGE: English  
 ENTRY DATE: Entered STN: 15 Aug 2001  
 Last Updated on STN: 19 Feb 2002

TI Hepatitis B vaccine in infants: A randomized controlled trial comparing gluteal versus anterolateral thigh muscle administration.  
 SO Revista do Instituto de Medicina Tropical de Sao Paulo, (May-June, 2001) Vol. 43, No. 3, pp. 139-143. print.  
 CODEN: RMTSAE. ISSN: 0036-4665.  
 AU Alves, Andrea Santos Rafael; Nascimento, Cristiane M. R.; Granato, Celso H.; Sato, Helena Keiko; Morgato, Marina F.; Pannuti, Claudio S. [Reprint author]  
 AB A significantly diminished antibody response to hepatitis B vaccine has been demonstrated in adults when the buttock is used as the **injection** site. However, in Brazil, the buttock continues to be recommended as site of **injection** for intramuscular administration of vaccines in infants. In this age group, there are no controlled studies evaluating the immunogenicity of the hepatitis B vaccine when administered at this site. In the present study, 258 infants were randomized to receive the hepatitis B vaccine either in the buttock (n = 123) or in the anterolateral **thigh** muscle (n = 135). The **immunization** schedule consisted of three doses of hepatitis B vaccine (Engerix B(R), 10 mug) at 2, 4 and 9 months of age. There were no significant differences in the proportion of seroconversion (99.3% X 99.2%), or in the geometric mean titer of ELISA anti-HBs (1,862.1 X 1,229.0 mIU/mL) between the two groups. This study demonstrates that a satisfactory serological response can be obtained when the hepatitis B vaccine is administered intramuscularly into the buttock.

L8 ANSWER 11 OF 19 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN  
 ACCESSION NUMBER: 2002:612530 BIOSIS  
 DOCUMENT NUMBER: PREV200200612530  
 TITLE: Safety and immunogenicity of pneumococcal conjugate vaccine  
 in combination with diphtheria, tetanus toxoid, pertussis  
 and Haemophilus influenzae type b conjugate vaccine.  
 AUTHOR(S): Obaro, Stephen K. [Reprint author]; Enwere, Godwin C.;  
 Deloria, Maria; Jaffar, Shabbar; Goldblatt, David;  
 Brainsby, Kate; Hallander, Hans; Mcinnes, Pamela;  
 Greenwood, Brian M.; McAdam, Keith P. W. J.  
 CORPORATE SOURCE: Imperial College School of Medicine, London, UK  
 SOURCE: Pediatric Infectious Disease Journal, (October, 2002) Vol.  
 21, No. 10, pp. 940-946. print.  
 ISSN: 0891-3668.  
 DOCUMENT TYPE: Article  
 LANGUAGE: English  
 ENTRY DATE: Entered STN: 27 Nov 2002  
 Last Updated on STN: 27 Nov 2002

TI Safety and immunogenicity of pneumococcal conjugate vaccine in combination  
 with diphtheria, tetanus toxoid, pertussis and Haemophilus influenzae type  
 b conjugate vaccine.

SO Pediatric Infectious Disease Journal, (October, 2002) Vol. 21, No. 10, pp.  
 940-946. print.  
 ISSN: 0891-3668.

AU Obaro, Stephen K. [Reprint author]; Enwere, Godwin C.; Deloria, Maria;  
 Jaffar, Shabbar; Goldblatt, David; Brainsby, Kate; Hallander, Hans;  
 Mcinnes, Pamela; Greenwood, Brian M.; McAdam, Keith P. W. J.

AB Background: Pneumococcal polysaccharide/protein conjugate vaccines (PnCV)  
 are immunogenic and effective in infancy. However, an addition to the  
 nine currently recommended vaccine **injections** during the first  
 year of life of African children may be a deterrent to participation in a  
 PnCV program. Thus we have evaluated the safety and immunogenicity of a  
 9-valent PnCV (Wyeth Lederle Pediatrics and Vaccines) mixed with  
 diphtheria, tetanus toxoid, cell pertussis and Haemophilus influenzae type  
 b (TETRAMUNE). Methods: Healthy Gambian infants were randomized at the  
 age of 2 months to receive three doses 1 month apart of either (1) placebo  
 reconstituted in TETRAMUNE in the right **thigh** (control) or (2)  
 PnCV in the left **thigh** and TETRAMUNE in the right **thigh**  
 (separate) or (3) PnCV reconstituted in TETRAMUNE as a single  
**injection** in the right **thigh** (combined). The vaccines  
 were given together with routine Expanded Program on **Immunization**  
 vaccines. Adverse reactions were recorded after vaccination, and antibody  
 concentrations were measured by enzyme-linked immunosorbent assays.  
 Results: Local induration and tenderness were observed more commonly at  
 the site of **injection** of TETRAMUNE than at the site of  
**injection** with PnCV after each dose of vaccination. Swelling at  
 the site of **injection** was encountered more frequently at the  
 site of administration of TETRAMUNE than at the site of administration  
 PnCV ( $P < 0.00001$  for Doses 1 and 2 and  $P < 0.0009$  for Dose 3). Swelling at  
 the site of administration of TETRAMUNE mixed with PnCV was comparable  
 with that observed for TETRAMUNE alone. Although most mothers reported  
 that the babies "felt hot" 24 h after each **injection**, febrile  
 reactions (temperature,  $gtoreq 38^{\circ}\text{C}$ ) were infrequent and resolved with  
 antipyretics. Geometric mean titer for anti-polyribosylribitol phosphate  
 antibody was 11.6 mug/ml (95% confidence limits (95% CI), 9.2, 14.6) in  
 the control group and comparable with 13.3 mug/ml (95% CI 11.0, 16.0) in  
 the combined group and significantly higher at 17.9 mug/ml (95% CI 14.7,  
 21.9;  $P = 0.01$ ) in the separate group. Geometric mean concentrations of  
 serotype-specific pneumococcal antibodies were higher in the combined  
 group than the separate group for all nine serotypes. Antibody responses  
 to diphtheria and pertussis antigens were similar in all groups.  
 Anti-tetanus toxoid antibody concentrations were lowest in the combined  
 group (6.66 IU/ml, 95% CI 5.77, 7.68 in the control group; 5.15 IU/ml, 95%  
 CI 4.39, 6.03 in the combined group;  $P = 0.02$ ). However, all vaccinees

achieved protective antibody values. Conclusion: The combination of TETRAMUNE and PnCV is safe and immunogenic.

L6 ANSWER 16 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN  
ACCESSION NUMBER: 1989:341768 BIOSIS  
DOCUMENT NUMBER: PREV198988044768; BA88:44768  
TITLE: ADVERSE REACTIONS TO DIPHTHERIA TETANUS PERTUSSIS-POLIO  
**VACCINATION** AT 18 MONTHS OF AGE EFFECT OF INJECTION  
SITE AND NEEDLE LENGTH.

AUTHOR(S): IPP M M [Reprint author]; GOLD R; GOLDBACH M; MARESKY D C;  
SAUNDERS N; GREENBERG S; DAVY T

CORPORATE SOURCE: DEP PEDIATRICS, UNIV TORONTO, HOSP SICK CHILDREN, 555  
UNIVERSITY AVENUE, TORONTO, ONTARIO, CANADA M5G 1X8

SOURCE: Pediatrics, (1989) Vol. 83, No. 5, pp. 679-682.

CODEN: PEDIAU. ISSN: 0031-4005.

DOCUMENT TYPE: Article

FILE SEGMENT: BA

LANGUAGE: ENGLISH

ENTRY DATE: Entered STN: 20 Jul 1989

Last Updated on STN: 20 Jul 1989

TI ADVERSE REACTIONS TO DIPHTHERIA TETANUS PERTUSSIS-POLIO  
**VACCINATION** AT 18 MONTHS OF AGE EFFECT OF INJECTION SITE AND  
NEEDLE LENGTH.

SO Pediatrics, (1989) Vol. 83, No. 5, pp. 679-682.  
CODEN: PEDIAU. ISSN: 0031-4005.

AU IPP M M [Reprint author]; GOLD R; GOLDBACH M; MARESKY D C; SAUNDERS N;  
GREENBERG S; DAVY T

AB Adverse reactions after diphtheria, pertussis, tetanus, polio  
**vaccination** at 18 months of age were investigated in three groups:  
74 children injected in the deltoid muscle with a 16-mm (5/8-in) needle,  
64 in the anterolateral **thigh** with a 16-mm needle, and 67 in the  
anterolateral **thigh** with a 25-mm (1-in) needle. No significant  
differences in systemic reactions were observed. Severe pain occurred in  
30.5% of the groups injected in the **thigh** compared with only  
8.1% of the group injected in the arm ( $P < .001$ ). Children vaccinated in  
the **thigh** had decreased movement of the extremity significantly  
more often than those injected in the arm (49.9% v 25.6%,  $P < .005$ ), and  
two thirds of the former limped for 24 to 48 hours. Redness and swelling  
were observed more often after **injection** in the arm than in the  
**thigh** (58.1% v 26.7%,  $P < .0005$ ). The only effect of changing  
needle length in the groups injected in the **thigh** was the  
occurrence of more redness and swelling in children vaccinated with the  
16-mm needle compared with the 25-mm needle. Overall, parents rated more  
reactions as moderate to severe among children injected in the  
**thigh** than among children injected in the arm (64.2% v 37.9%,  $P < .001$ ). The deltoid muscle appears to be the preferred site for  
administration of diphtheria, pertussis, tetanus, polio vaccine at 18 months  
of age

ACCESSION NUMBER: 1997:43522 BIOSIS

DOCUMENT NUMBER: PREV199799335510

TITLE: Randomised trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine.

AUTHOR(S): Eskola, Juhani [Reprint author]; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena

CORPORATE SOURCE: National Public Health Inst., 00300 Helsinki, Finland

SOURCE: Lancet (North American Edition), (1996) Vol. 348, No. 9043, pp. 1688-1692.

ISSN: 0099-5355.

DOCUMENT TYPE: Article

LANGUAGE: English

ENTRY DATE: Entered STN: 28 Jan 1997

Last Updated on STN: 28 Jan 1997

TI Randomised trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine.

SO Lancet (North American Edition), (1996) Vol. 348, No. 9043, pp. 1688-1692. ISSN: 0099-5355.

AU Eskola, Juhani [Reprint author]; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena

AB Background: Inclusion of new vaccines in **vaccination** programmes for children would be easier if they could be combined with existing vaccines. Vaccines containing acellular pertussis in the diphtheria/tetanus/pertussis (DTP-a) combination are expected to replace the conventional whole-cell vaccines (DTP-w). We tested the immunogenicity and safety of a combination of DTP-a with the Haemophilus influenzae type b (Hib) conjugate of Hib capsular polysaccharide and tetanus toxoid (PRP-T), and inactivated poliovirus vaccine (IPV). Methods: 120 infants were enrolled and randomised to four groups to receive DTP-a at ages 2, 4, and 6 months. At 4 and 6 months they also received Hib conjugate and IPV, either as separate **injections** or mixed with DTP-a. All **injections** were given intramuscularly in the anterolateral area of the **thigh**. Any reactions after each **vaccination** were noted by the parents. EIA was used to measure titres of diphtheria, tetanus, and pertussis antibodies, RIA for Hib anticapsular antibodies, and microneutralisation assay for poliovirus antibodies from serum samples collected at the ages of 2, 4, 6, and 7 months. Findings: There were 30 infants in each group. Only mild adverse events were reported. There was a tendency towards slightly lower concentrations of filamentous haemagglutinin, tetanus, and poliovirus 1 antibodies when the vaccines were mixed. However, there was a more pronounced difference ( $p=4 \times 10^{-8}$ ) in Hib antibodies between groups receiving Hib capsular polysaccharide mixed with DTP-a (geometric mean concentrations 0.37  $\mu\text{g/mL}$  and 0.56  $\mu\text{g/mL}$ ) compared with groups receiving the vaccines separately (3.10  $\mu\text{g/mL}$  and 3.94  $\mu\text{g/mL}$ ). Interpretation: Administration of premixed DTP-a, Hib conjugate, and IPV affect the immune response significantly. The mechanism of this interference is not clear. The immunogenicity of all antigens must be tested before new combinations can be accepted for **vaccination** programmes for infants.

L6 ANSWER 10 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN  
 ACCESSION NUMBER: 1999:398314 BIOSIS  
 DOCUMENT NUMBER: PREV199900398314  
 TITLE: Information to be provided to parents of children to be vaccinated with diphtheria-tetanus-pertussis acellular vaccine.  
 AUTHOR(S): Tozzi, A. E. [Reprint author]; Ciofi degli Atti, M. L.; Salmaso, S.; Anemona, A.; Parrocchini, S.  
 CORPORATE SOURCE: Laboratorio di Epidemiologia e Biostatistica, Istituto Superiore di Sanita, Reparto Malattie Infettive, V.le Regina Elena, 299, 00161, Roma, Italy  
 SOURCE: Igiene Moderna, (April, 1999) Vol. 111, No. 4, pp. 391-400. print.  
 CODEN: IGMPAX. ISSN: 0019-1655.  
 DOCUMENT TYPE: Article  
 LANGUAGE: Italian  
 ENTRY DATE: Entered STN: 8 Oct 1999  
 Last Updated on STN: 8 Oct 1999  
 TI Information to be provided to parents of children to be vaccinated with diphtheria-tetanus-pertussis acellular vaccine.  
 SO Igiene Moderna, (April, 1999) Vol. 111, No. 4, pp. 391-400. print.  
 CODEN: IGMPAX. ISSN: 0019-1655.  
 AU Tozzi, A. E. [Reprint author]; Ciofi degli Atti, M. L.; Salmaso, S.; Anemona, A.; Parrocchini, S.  
 AB The data provided by the Progetto Pertosse, a study on 15,601 children immunized with whole-cell or acellular diphtheria-tetanus-pertussis vaccines, or with a diphtheria-tetanus vaccine, allowed to gather detailed information on adverse reactions which can occur after the administration of the acellular vaccines used in Italy. Families of pertussis vaccinees should be informed in detail of expected adverse reactions. The results from Progetto Pertosse show that the reactogenicity of acellular vaccines is much lower than that observed with whole-cell vaccines, and similar to diphtheria-tetanus vaccines. The most common adverse events such as fever and local reactions start and end in most cases within 2 days of administration, and in the majority of cases have a short duration. The simultaneous administration of polio and hepatitis B vaccines does not increase the reactogenicity and does not affect the efficacy of acellular vaccines. **Injection** in the buttock is associated with a lower probability of observing common adverse reactions when compared to **injection** in the **thigh**. Children who experienced an adverse reaction are more likely to present the same event at following doses. Appropriate information to parents of vaccinees on the safety of acellular pertussis vaccines is necessary, it is useful to reassure the families of vaccinees and avoid interruptions of the immunization series due to false contraindications.

L6 ANSWER 8 OF 18 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN  
ACCESSION NUMBER: 2001:386015 BIOSIS  
DOCUMENT NUMBER: PREV200100386015  
TITLE: Reactogenicity of DTPa-HBV/Hib vaccine administered as a  
single injection vs DTPa-HBV and Hib vaccines administered  
simultaneously at separate sites, to infants at 2, 4 and 6  
months of age.  
AUTHOR(S): Omenaca, F.; Dal-Re, R. [Reprint author]; D'Apuzzo, V.;  
Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.;  
Garcia-Corbeira, P.  
CORPORATE SOURCE: Medical Department, SmithKline Beecham Pharmaceuticals,  
c/Dr Severo Ochoa 2, 28760 Tres Cantos, Madrid, Spain  
rafael.dal-re@gsk.com  
SOURCE: Vaccine, (20 July, 2001) Vol. 19, No. 30, pp. 4260-4266.  
print.  
CODEN: VACCDE. ISSN: 0264-410X.  
DOCUMENT TYPE: Article  
LANGUAGE: English  
ENTRY DATE: Entered STN: 15 Aug 2001  
Last Updated on STN: 19 Feb 2002

TI Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection  
vs DTPa-HBV and Hib vaccines administered simultaneously at separate  
sites, to infants at 2, 4 and 6 months of age.  
SO Vaccine, (20 July, 2001) Vol. 19, No. 30, pp. 4260-4266. print.  
CODEN: VACCDE. ISSN: 0264-410X.  
AU Omenaca, F.; Dal-Re, R. [Reprint author]; D'Apuzzo, V.; Kattamis, C.;  
Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.  
AB An open, randomised, multicentre trial was performed to assess the  
reactogenicity and safety profile of the administration of a candidate  
Haemophilus influenzae type b (Hib) conjugate vaccine with a quadrivalent  
diphtheria-tetanus-acellular pertussis-hepatitis B (DTPa-HBV) vaccine as a  
single **injection** (Group 1) versus the simultaneous  
administration of the latter vaccine (DTPa-HBV) and an available Hib  
conjugate vaccine (Group 2) in opposite **thighs**, as a primary  
**vaccination** course to healthy infants at 2, 4 and 6 months of age.  
Eight hundred and eighty five infants (9.3+-1.4 weeks old) were randomly  
allocated to Group 1 (n=665) and Group 2 (n=221). Oral polio vaccine was  
given concomitantly to all subjects. Blood samples (pre-  
**vaccination** and 1 month after the third dose) were obtained from a  
subset of infants (Group 1, 73; Group 2, 22) for serological  
determinations. Local and general symptoms were recorded by parents on  
diary cards. 2614 diary cards (Group 1, 1966; Group 2, 648) were  
collected. There were no statistically significant differences in the  
incidence of local and general symptoms between groups. Pain such that  
the infant cried when limb was moved was reported in 0.6 and 0.2% in  
groups 1 and 2, respectively. Redness and swelling (>20 mm in diameter)  
were recorded between 2.1 and 3% in both groups. Fussiness preventing  
normal activities was the most frequently reported general symptom in both  
groups (1.6 and 1.9% in groups 1 and 2, respectively). Fever (rectal  
temperature >39.5degreeC) was reported in 0.4% (Group 1) and 0.3% (Group  
2). All subjects included in the immunogenicity analysis had  
seroprotective or seropositive titres to the diphtheria, tetanus,  
hepatitis B and pertussis components of the vaccines. About 99 and 100%  
of infants had anti-PRP titres gtoreq0.15 mcg/ml in groups 1 and 2,  
respectively. This study indicates that DTPa-HBV vaccine given in a  
single **injection** with a candidate Hib conjugate vaccine has a  
similar reactogenicity profile to that of two commercially available  
vaccines (DTPa-HBV, Hib) given in two simultaneous **injections** to  
infants 2, 4 and 6 months of age.



ACCESSION NUMBER: 2003:457990 BIOSIS

DOCUMENT NUMBER: PREV200300457990

TITLE: Comparison of the reactogenicity and immunogenicity of a combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio (DTPa-HBV-IPV) vaccine, mixed with the Haemophilus influenzae type b (Hib) conjugate vaccine and administered as a single injection, with the DTPa-IPV/Hib and hepatitis B vaccines administered in two simultaneous injections to infants at 2, 4 and 6 months of age.

AUTHOR(S): Aristegui, J.; Dal-Re, R.; Diez-Delgado, J.; Mares, J.; Casanovas, J. M.; Garcia-Corbeira, P. [Reprint Author]; De Frutos, E.; Van Esso, D.; Verdaguer, J.; de la Flor, J.; Moraga, F.; Boceta, R.; Garcia-Martinez, J. A.

CORPORATE SOURCE: Medical Department, GlaxoSmithKline, c/Severo Ochoa 2, Tres Cantos, PTM, 28760, Madrid, Spain  
pilar.garcia-corbeira@gsk.com

SOURCE: Vaccine, (8 September 2003) Vol. 21, No. 25-26, pp. 3593-3600. print.

ISSN: 0264-410X (ISSN print).

DOCUMENT TYPE: Article

LANGUAGE: English

ENTRY DATE: Entered STN: 8 Oct 2003

Last Updated on STN: 8 Oct 2003

TI Comparison of the reactogenicity and immunogenicity of a combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated polio (DTPa-HBV-IPV) vaccine, mixed with the Haemophilus influenzae type b (Hib) conjugate vaccine and administered as a single injection, with the DTPa-IPV/Hib and hepatitis B vaccines administered in two simultaneous injections to infants at 2, 4 and 6 months of age.

SO Vaccine, (8 September 2003) Vol. 21, No. 25-26, pp. 3593-3600. print.  
ISSN: 0264-410X (ISSN print).

AU Aristegui, J.; Dal-Re, R.; Diez-Delgado, J.; Mares, J.; Casanovas, J. M.; Garcia-Corbeira, P. [Reprint Author]; De Frutos, E.; Van Esso, D.; Verdaguer, J.; de la Flor, J.; Moraga, F.; Boceta, R.; Garcia-Martinez, J. A.

AB An open, randomised, multicentre trial was performed to compare the reactogenicity and safety profile of the administration of a hexavalent diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated polio (DTPa-HBV-IPV) vaccine administered in one **injection** mixed with Haemophilus influenzae type b (Hib) conjugate vaccine (Group 1) with that of a pentavalent DTPa-IPV vaccine mixed with a Hib vaccine (DTPa-IPV/Hib), simultaneously administered with HBV (Group 2) in two **injections** in opposite **thighs**, as a primary **vaccination** course, to healthy infants at 2, 4 and 6 months of age. A total of 235 completed the study, 120 from Group 1 and 115 from Group 2. Blood samples (pre-**vaccination** and 1 month after the third dose) were obtained from a subset of infants (Group 1: 40; Group 2: 31) to assess the immune response to **vaccination**. Local and general solicited symptoms were recorded by parents on diary cards. Seven hundred and five diary cards (Group 1: 360; Group 2: 345) were collected. The clinically relevant and most commonly reported local reaction was pain (infant cried when the limb was moved) in 2.5% (Group 1) and 1.2% (Group 2) of diary cards. Fever was more frequently reported in Group 1 (21% of diary cards) than in Group 2 (12% of diary cards). However only 3 and 2% of doses in Groups 1 and 2, respectively, were responsible for a rectal temperature between 38.6 and 39.5 degreeC and only one case (Group 2) had gtoreq 39.5 degreeC. Other clinically relevant general symptoms were rarely recorded: irritability (2-2.8%), loss of appetite (0.3-0.6%) and drowsiness (0.3-0.3%). All subjects included in the immunogenicity analysis had seroprotective titres to diphtheria, tetanus, polio virus types 1 and 3, Hib. Almost all subjects were seroprotected for anti-polio type 2 and hepatitis B (with the exception of 1 subject in Group 1 for each antigen). The vaccines

response rates to pertussis antigens were over 97 and 90% in Groups 1 and 2, respectively. This study shows that, from a clinical perspective, the DTPa-HBV-IPV/Hib vaccine given in a single **injection** has a similar reactogenicity and safety profile to that of two licensed vaccines (DTPa-IPV/Hib, HBV) given in two simultaneous **injections** to infants at 2, 4 and 6 months of age. This is a valuable advantage, since in some countries, such as Spain and the UK, an additional **injection** (for the administration of meningococcal C conjugate vaccine) has been recently included in the infants' **vaccination** calendars.

ACCESSION NUMBER: 1997:59715 CAPLUS  
 DOCUMENT NUMBER: 126:102765  
 TITLE: Randomized trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine  
 AUTHOR(S): Eskola, Juhani; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena  
 CORPORATE SOURCE: National Public Health Institute, Helsinki, 00300, Finland  
 SOURCE: Lancet (1996), 348(9043), 1688-1692  
 CODEN: LANCAO; ISSN: 0140-6736  
 PUBLISHER: Lancet  
 DOCUMENT TYPE: Journal  
 LANGUAGE: English

TI Randomized trial of the effect of co-administration with acellular pertussis DTP vaccine on immunogenicity of Haemophilus influenzae type b conjugate vaccine  
 SO Lancet (1996), 348(9043), 1688-1692  
 CODEN: LANCAO; ISSN: 0140-6736  
 AU Eskola, Juhani; Olander, Rose-Marie; Hovi, Tapani; Litmanen, Leila; Peltola, Sara; Kayhty, Helena  
 AB Inclusion of new vaccines in **vaccination** programs for children would be easier if they could be combined with existing vaccines. Vaccines containing acellular pertussis in the diphtheria/tetanus/pertussis (DTP-a) combination are expected to replace the conventional whole-cell vaccines (DTP-w). We tested the immunogenicity and safety of a combination of DTP-a with the Haemophilus influenzae type b (Hib) conjugate of Hib capsular polysaccharide and tetanus toxoid (PRP-T), and inactivated poliovirus vaccine (IPV). Methods 120 infants were enrolled and randomized to four groups to receive DTP-a at ages 2, 4, and 6 mo. At 4 and 6 mo they also received Hib conjugate and IPV, either as sep. **injections** or mixed with DTP-a. All **injections** were given i.m. in the anterolateral area of the **thigh**. Any reactions after each **vaccination** were noted by the parents. EIA was used to measure titers of diphtheria, tetanus, and pertussis antibodies, RIA for Hib anticapsular antibodies, and microneutralization assay for poliovirus antibodies from serum samples collected at the ages of 2, 4, 6, and 7 mo. Findings There were 30 infants in each group. Only mild adverse events were reported. There was a tendency towards slightly lower concns. of filamentous hemagglutinin, tetanus, and poliovirus 1 antibodies when the vaccines were mixed. However, there was a more pronounced difference ( $p=4+10^{-8}$ ) in Hib antibodies between groups receiving Hib capsular polysaccharide mixed with DTP-a (geometric mean concns.  $0\sum 37 \mu\text{g/mL}$  and  $0\sum 56 \mu\text{g/mL}$ ) compared with groups receiving the vaccines sep. ( $3\sum 10 \mu\text{g/mL}$  and  $3\sum 94 \mu\text{g/mL}$ ). Interpretation Administration of premixed DTP-a, Hib conjugate, and IPV affect the immune response significantly. The mechanism of this interference is not clear. The immunogenicity of all antigens must be tested before new combinations can be accepted for **vaccination** programs for infants.

ACCESSION NUMBER: 2001:520223 CAPLUS  
 DOCUMENT NUMBER: 136:230830  
 TITLE: Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age  
 AUTHOR(S): Omenaca, F.; Dal-Re, R.; D'Apuzzo, V.; Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.  
 CORPORATE SOURCE: The European DTPa-HBV/Hib 041 Study Group, Departments of Neonatology and Paediatrics, La Paz Hospital, Madrid, Spain  
 SOURCE: Vaccine (2001), 19(30), 4260-4266  
 CODEN: VACCDE; ISSN: 0264-410X  
 PUBLISHER: Elsevier Science Ltd.  
 DOCUMENT TYPE: Journal  
 LANGUAGE: English

TI Reactogenicity of DTPa-HBV/Hib vaccine administered as a single injection vs DTPa-HBV and Hib vaccines administered simultaneously at separate sites, to infants at 2, 4 and 6 months of age  
 SO Vaccine (2001), 19(30), 4260-4266  
 CODEN: VACCDE; ISSN: 0264-410X  
 AU Omenaca, F.; Dal-Re, R.; D'Apuzzo, V.; Kattamis, C.; Gnehm, H. P.; Garcia-Sicilia, J.; Garcia-Corbeira, P.  
 AB An open, randomized, multicenter trial was performed to assess the reactogenicity and safety profile of the administration of a candidate Haemophilus influenzae type b (Hib) conjugate vaccine with a quadrivalent diphtheria-tetanus-acellular pertussis-hepatitis B (DTPa-HBV) vaccine as a single **injection** (Group 1) vs. the simultaneous administration of the latter vaccine (DTPa-HBV) and an available Hib conjugate vaccine (Group 2) in opposite **thighs**, as a primary **vaccination** course to healthy infants at 2, 4 and 6 mo of age. Eight hundred and eighty five infants (9.3±1.4 wk old) were randomly allocated to Group 1 (n=665) and Group 2 (n=221). Oral polio vaccine was given concomitantly to all subjects. Blood samples (pre-**vaccination** and 1 mo after the third dose) were obtained from a subset of infants (Group 1, 73; Group 2, 22) for serol. detns. Local and general symptoms were recorded by parents on diary cards. 2614 diary cards (Group 1, 1966; Group 2, 648) were collected. There were no statistically significant differences in the incidence of local and general symptoms between groups. Pain such that the infant cried when limb was moved was reported in 0.6 and 0.2% in groups 1 and 2, resp. Redness and swelling (>20 mm in diameter) were recorded between 2.1 and 3% in both groups. Fussiness preventing normal activities was the most frequently reported general symptom in both groups (1.6 and 1.9% in groups 1 and 2, resp.). Fever (rectal temperature >39.5°C) was reported in 0.4% (Group 1) and 0.3% (Group 2). All subjects included in the immunogenicity anal. had seroprotective or seropos. titers to the diphtheria, tetanus, hepatitis B and pertussis components of the vaccines. About 99 and 100% of infants had anti-PRP titers ≥0.15 mcg/mL in groups 1 and 2, resp. This study indicates that DTPa-HBV vaccine given in a single **injection** with a candidate Hib conjugate vaccine has a similar reactogenicity profile to that of two com. available vaccines (DTPa-HBV, Hib) given in two simultaneous **injections** to infants 2, 4 and 6 mo of age.

REFERENCE COUNT: 23 THERE ARE 23 CITED REFERENCES

L8 ANSWER 13 OF 19 BIOSIS COPYRIGHT 2004 BIOLOGICAL ABSTRACTS INC. on STN  
 ACCESSION NUMBER: 1999:398314 BIOSIS  
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 TITLE: Information to be provided to parents of children to be  
 vaccinated with diphtheria-tetanus-pertussis acellular  
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 AUTHOR(S): Tozzi, A. E. [Reprint author]; Ciofi degli Atti, M. L.;  
 Salmaso, S.; Anemona, A.; Parroccini, S.  
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 AU Tozzi, A. E. [Reprint author]; Ciofi degli Atti, M. L.; Salmaso, S.;  
 Anemona, A.; Parroccini, S.  
 AB The data provided by the Progetto Pertosse, a study on 15,601 children  
 immunized with whole-cell or acellular diphtheria-tetanus-pertussis  
 vaccines, or with a diphtheria-tetanus vaccine, allowed to gather detailed  
 information on adverse reactions which can occur after the administration  
 of the acellular vaccines used in Italy. Families of pertussis vaccinees  
 should be informed in detail of expected adverse reactions. The results  
 from Progetto Pertosse show that the reactogenicity of acellular vaccines  
 is much lower than that observed with whole-cell vaccines, and similar to  
 diphtheria-tetanus vaccines. The most common adverse events such as fever  
 and local reactions start and end in most cases within 2 days of  
 administration, and in the majority of cases have a short duration. The  
 simultaneous administration of polio and hepatitis B vaccines does not  
 increase the reactogenicity and does not affect the efficacy of acellular  
 vaccines. **Injection** in the buttock is associated with a lower  
 probability of observing common adverse reactions when compared to  
**injection** in the **thigh**. Children who experienced an  
 adverse reaction are more likely to present the same event at following  
 doses. Appropriate information to parents of vaccinees on the safety of  
 acellular pertussis vaccines is necessary, it is useful to reassure the  
 families of vaccinees and avoid interruptions of the **immunization**  
 series due to false contraindications.